holders in other countries until it completes this "18 by 87" project. In the meantime, arrangements have been made for the European Patent Office to prepare the examination reports for U.S. applicants during the interim.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S. 1230

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Act to Authorize the United States to Participate in Chapter II of the Patent Cooperation Treaty."

SEC. 2. (a) Section 351(a) of title 35, United States Code, is amended by striking out ", excluding chapter II thereof".

(b) Section 351(b) of title 35, United States Code, is amended by striking out "excluding part C thereof".

(c) Section 351(g) of title 35, United States Code, is amended by—

(1) striking out "term" and inserting in lieu thereof "terms";

(2) inserting "and 'International Preliminary Examining Authority' " after "Authority"; and

(3) striking out "means" and inserting in lieu thereof "mean".

(d) Section 361(d) of title 35, United States Code, is amended to read as follows:

"(d) The international fee, and the transmittal and search fees prescribed under section 376(a) of this part, shall either be paid on filing of an international application or within such later time as may be fixed by the Commissioner."

SEC. 3. The item relating to section 362 in the analysis for chapter 36 of title 35, United States Code, is amended to read as follows:

"362. International Searching Authority and International Preliminary Examining Authority."

SEC. 4. Section 362 of title 35, United States Code, is amended to read as follows:

"Sec. 362. International Searching Authority and International Preliminary Examining Authority

"(a) The Patent and Trademark Office may act as an International Searching Authority and International Preliminary Examining Authority with respect to international applications in accordance with the terms and conditions of an agreement which may be concluded with the International Bureau, and may discharge all duties required of such Authorities, including the collection of handling fees and their transmittal to the International Bureau.

"(b) The handling fee, preliminary examination fee, and any additional fees due for international preliminary examination shall be paid within such time as may be fixed by the Commissioner."

SEC. 5. Section 364(a) of title 35, United States Code, is amended by—

(a) striking out "or", first occurrence and inserting in lieu thereof ",";

(b) inserting "International Preliminary Examining Authority" after "Authority, or"; and

(c) striking out "both".

SEC. 6. Section 368(c) of title 35, United States Code, is amended by—

(a) striking out the second occurrence of "or" and inserting in lieu thereof ","; and

(b) striking out "both" and inserting in lieu thereof "International Preliminary Examining Authority".

SEC. 7. (a) Section 371(a) of title 35, United States Code, is amended to read as follows:

"(a) Receipt from the International Bureau of copies of international applications with any amendments to the claims, international search reports, and international preliminary examination reports including any annexes thereto may be required in the case of international applications designating or electing the United States."

(b) Section 371(b) of title 35, United States Code, is amended to read as follows:

"(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39(1)(a) of the treaty."

(c) Section 371(c)(4) of title 35, United States Code, is amended by striking the "." and inserting in lieu therefore ";".

(d) Section 371(c) of title 35, United States Code, is amended by adding at the end thereof the following new paragraph (5):

"(5) a translation into the English language of any annexes to the international preliminary examination report, if such annexes were made in another language.".

(e) Section 371(d) of title 35, United States Code, is amended by adding at the end thereof the following sentence:

"The requirement of subsection (c)(5) shall be complied with at such time as may be fixed by the Commissioner and failure to do so shall be regarded as cancellation of the amendments made under article 34(2)(b) of the treaty.".

(f) Section 371(e) of title 35, United States Code, is amended by inserting "or article 41" after "28".

SEC. 8. (a) Section 376(a) of title 35, United States Code, is amended by—

(1) inserting "and the handling fee" after the first occurrence of "fee";

(2) striking "amount is" and inserting in lieu thereof "amounts are";

(3) redesignating paragraph (5) as paragraph (6); and

(4) inserting the following new paragraph (5):

"(5) A preliminary examination fee and any additional fees (see section 362(b))."

(b) Section 376(b) of title 35, United States Code, is amended by—

(1) inserting "and the handling fee" after the first occurrence of "fee" in the first sentence; and

(2) inserting "the preliminary examination fee and any additional fees," after "fee," in the third sentence.

SEC. 9. Sections 2 through 8 of this Act shall come into force on the same day as the effective date of entry into force of chapter II of the Patent Cooperation Treaty with respect to the United States, by virtue of the withdrawal of the declaration under article 64(1)(a) of the Patent Cooperation Treaty. It shall apply to all international applications pending before or after its effective date.

By Mr. DOLE (for himself and Mr. HEINZ):

S. 1233. A bill to amend the Animal Welfare Act to ensure the proper treatment of laboratory animals; to the Committee on Agriculture, Nutrition, and Forestry.

IMPROVED STANDARDS FOR LABORATORY ANIMALS ACT

Mr. DOLE. Mr. President, we are pleased today to introduce S. 1233, the Improved Standards for Laboratory Animals Act as an amendment to the Animal Welfare Act [AWA] and to be joined as a cosponsor by my distinguished colleague Senator HEINZ.

The bill we are introducing today is similar to legislation my colleagues and I introduced in the Senate during the last session of Congress and which, I understand, will again be introduced in the House by Congressman GEORGE BROWN this week.

BACKGROUND OF LEGISLATION

Mr. President, we have had ample opportunity to discuss the substance of this legislation in Congress. The legislation being introduced today has undergone several changes since the original version was introduced in the 97th Congress with a modified version subsequently introduced in the 98th Congress.

It is a product of numerous Senate and House staff meetings with representatives of both the animal welfare community and the scientific community. I believe this bill represents a fair and reasonable attempt to balance the public's concern over the welfare of animals with the need to continue achieving medical advancements which benefit the lives and health of both man and animals.

A REASONABLE APPROACH

In addition to the numerous meetings that took place to arrive at a concensus on this issue, hearings were also held in both the House and Senate during the last session of Congress. Throughout the debate on this issue it has been pointed out that experimentation and testing on animals has benefited our society by yielding medical breakthroughs that have aided the development of new knowledge, new drugs, and better surgical techniques in addition to saving millions of lives.

It has also been pointed out that the use of animals will need to continue for the time being until alternative methodologies which do not use animals or which reduce the numbers of animals used and reduce the pain they experience can be further developed. At the same time, we need to ensure the public that adequate safeguards are in place to prevent unnecessary abuses to animals and that everything that is reasonably possible is being done to decrease the pain that animals suffer during experimentation and testing.

It is very likely that USDA could further improve their effectiveness in administrating the Animal Welfare Act if the improvements contained in this legislation are implemented.

Mr. President, I ask that a summary of the bill and the text of the bill be

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printed in the CONGRESSIONAL RECORD at the conclusion of my remarks and I urge my colleagues to support the legislation.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 1233

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Improved Standards for Laboratory Animals Act".

FINDINGS

SEC. 2. The Congress finds that—

(1) the use of animals has been instrumental in certain research and education for advancing knowledge of cures and treatments for diseases and injuries such afflict both humans and animals;

(2) methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experiments for some purposes and further opportunities exist for the development of these methods of testing;

(3) measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds; and

(4) measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress.

STANDARDS AND CERTIFICATION PROCESS

SEC. 3. (a) Section 13 of the Animal Welfare Act (7 U.S.C. 2143) is amended—

(1) by redesignating subsections (b) through (d) as subsections (f) through (h), respectively; and

(2) by striking out the first two sentences of subsection (a) and inserting in lieu thereof the following:

"(1) The Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, and exhibitors.

"(2) The standards described in paragraph (1) shall include requirements—

"(A) for handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperatures, and separation by species where the Secretary finds necessary for humane handling, care, or treatment of animals; and

"(B) For exercise of dogs.

"(3) In addition to the requirements under paragraph (2), the standards described in paragraph (1) shall, with respect to animals in research facilities include requirements—

"(A) for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized, including adequate veterinary care with the appropriate use of anesthetic, analgesic, tranquilizing drugs, or euthansia;

"(B) that the principal investigator considers alternatives to any procedure likely to produce pain to or distress in an experimental animal;

"(C) in any practice which could cause pain to animals—

"(i) that a doctor of veterinary medicine is consulted in the planning of such procedures;

"(ii) for the use of tranquilizers, analgesics, and anesthetics;

"(iii) for pre-surgical and post-surgical care by laboratory workers in accordance with established veterinary medical and nursing procedures;

"(iv) against the use of paralytics without anesthesia; and

"(v) that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time;

"(D) that no animal is used in more than one major operative experiment from which it is allowed to recover except in cases of—

"(i) scientific necessity; or

"(ii) other special circumstances are determined by the Secretary; and

"(E) that exceptions to such standards may be made only when specified by research protocol and that any such exception shall be detailed and justified in a report outlined under paragraph (7) and filed with the Institutional Animal Committee.".

(b) Section 13(a) of such Act is further amended—

(1) by designating the third and fourth sentences as paragraph (4);

(2) by designating the fifth sentence as paragraph (5); and

(3) by striking out the last sentence and inserting in lieu thereof the following:

"(6) Nothing in this Act shall be construed as authorizing the Secretary to promulgate rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility: *Provided*, That the Secretary shall require every research facility to show that professionally acceptable standards governing the care, treatment, and practices on animals are being followed by the research facility during research and experimentation.

"(7)(A) The Secretary shall require, at least annually, every research facility to report that the provisions of this Act are being followed.

"(B) In complying with subparagraph (A), the research facility shall provide—

"(i) the details of any procedure which was likely to produce pain or distress in any animal and assurances demonstrating that the principal investigator considered alternatives to those procedures;

"(ii) assurances satisfactory to the Secretary that such facility is adhering to the standards described in this section; and

"(iii) an explanation for any deviation from the standards promulgated under this section.

"(8) Paragraph (1) shall not prohibit any State (or a political subdivision of such State) from promulgating standards in addition to those standards promulgated by the Secretary under paragraph (1).".

(c) Section 13 of such Act is further amended by inserting after subsection (a) the following new subsections:

"(b)(1) The Secretary shall require that each research facility establish at least one Institutional Animal Committee. Each Committee shall be appointed by the chief executive officer of each such research facility and shall be composed of not fewer than three members. Such members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility. Of the members of the Committee—

"(A) at least one member shall be a doctor of veterinary medicine;

"(B) at least one member shall not be affiliated in any way with such facility other than as a member of the Committee, shall not be a member of the immediate family of a person who is affiliated with such facility, and shall be responsible for representing society's concerns regarding the welfare of the animal subjects; and

"(C) in those cases where the Committee consists of more than three members, not more than three members shall be from the same administrative unit of such facility.

"(2) A quorum shall be required for all formal actions of the Committee, including inspections under paragraph (3).

"(3) The Committee shall inspect at least semiannually all animal study areas and animal facilities of such research facility and review as part of the inspection—

"(A) practices involving pain to animals, and

"(B) the condition of animals,

to ensure compliance with the provisions of this Act and that pain and distress to animals is minimized. Exceptions to the requirement of inspection of such study areas may be made by the Secretary if animals are studies in their natural environment and the study area is prohibitive to easy access.

"(4)(A) The Committee shall file an inspection certification report of each inspection at the research facility. Such report shall—

"(i) be signed by a majority of the Committee members involved in the inspection;

"(ii) include reports of any violation of the standards promulgated, or assurances required, by the Secretary, including any deficient conditions of animal care or treatment, any deviations of research practices from originally approved proposals that adversely affect animal welfare, any notification to the facility regarding such conditions, and any corrections made thereafter;

"(iii) include any minority views of the Committee; and

"(iv) include any other information pertinent to the activities of the Committee.

"(B) Such report shall remain on file for at least three years at the research facility and shall be available for inspection by the Animal and Plant Health Inspection Service of the Department of Agriculture and any funding Federal agency.

"(C) In order to give the research facility an opportunity to correct any deficiencies or deviations discovered by reason of paragraph (3), the Committee shall notify the administrative representative of the research facility of any deficiencies or deviations from the provisions of this Act. If, after notification and an opportunity for correction, such deficiencies or deviations remain uncorrected, the Committee shall notify (in writing) the Animal and Plant Health Inspection Service of the Department of Agriculture and the funding Federal agency of such deficiencies or deviations.

"(5) The inspection results shall be available to Department of Agriculture inspectors for review during inspections. Department of Agriculture inspectors shall forward any committee inspection records which include reports of uncorrected deficiencies or deviations to the Animal and Plant Health Inspection Service of the Department of Agriculture and any funding Federal agency of the project with respect to which such uncorrected deficiencies and deviations occurred.

"(c)(1) The research facility shall provide for annual training for scientists, animal technicians, and other personnel involved with animal care and treatment in such facility. Such training shall include instruction on—

"(A) the humane practice of animal maintenance and experimentation:

"(B) research or testing methods that minimize or eliminate the use of animals or limit animal pain or distress; and

"(C) utilization of the information service at the National Agricultural Library, established under subsection (d).

"(2) Research facilities shall inform their employees of the provisions of this Act and shall inform such employees to report any violations of such provisions. Any such employee may not be discriminated against on grounds that such employee reported a violation of such provisions.

"(d) The Secretary shall establish an information service at the National Agricultural Library. Such service shall, in cooperation with the National Library of Medicine provide information—

"(1) pertinent to employee training,

"(2) which could prevent unintended duplication of animal experimentation as determined by the needs of the research facility, and

"(3) on improved methods of animal experimentation, including methods which could—

"(A) reduce or replace animal use; and

"(B) minimize pain and distress to animals such as anesthetic and analgesic procedures.

"(e) In any case in which the funding Federal agency determines that conditions of animal care, treatment, or practice in a particular project have not been in compliance with standards promulgated under this Act, despite notification by the Secretary or the funding Federal agency to the research facility and an opportunity for correction, such agency shall suspend or revoke Federal support for the project. Any research facility losing Federal support as a result of actions taken under the preceding sentence shall have the right of appeal as provided in sections 701 through 706 of title 5, United States Code.".

INSPECTIONS

SEC. 4. Section 16(a) of the Animal Welfare Act (7 U.S.C. 2146(a)) is amended by inserting after the first sentence the following:

"The Secretary shall inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this Act, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected.".

PENALTY FOR RELEASE OF TRADE SECRETS

SEC. 5. The Animal Welfare Act (7 U.S.C. 2131-2156) is amended by adding at the end thereof the following section:

"SEC. 27. (a) It shall be unlawful for any member of the Institutional Animal Committee to release any confidential information of the research facility, including any information that concerns or relates to—

"(1) the trade secrets, processes, operations, style of work, or apparatus, or

"(2) to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of the research facility.

"(b) It shall be unlawful for any member of such Committee—

"(1) to use or attempt to use to his advantage, or

"(2) to reveal to any other person, any information which is entitled to protection as confidential information under subsection (a).

"(c) A violation of subsection (a) or (b) is punishable by—

"(1) removal from such Committee, and

"(2)(A) a fine of not more than $1,000 and imprisonment of not more than one year, or

"(B) if such violation is willful, a fine of not more than $10,000 and imprisonment of not more than three years.

"(d) Any person, including any research facility, injured in its business or property by reason of a violation of this section may recover all actual and consequential damages sustained by such person and the cost of the suit including a reasonable attorney's fee.

"(e) Nothing in this section shall be construed to affect any other rights that any such person may have, nor shall subsection (d) be construed to limit the exercise of any such rights arising out of or relating to a violation of subsection (a) and (b).'

INCREASED PENALTIES FOR VIOLATION OF THE ACT

SEC. 6. Subsection (b) of section 19 of the Animal Welfare Act (7 U.S.C. 2149(b)) is amended—

(1) in the first sentence by striking out "$1,000 for each such violation" and inserting in lieu thereof "$2,500 for each such violation"; and

(2) in the sixth sentence by striking out "$500 for each offense" and inserting in lieu thereof "$1,000 for each offense"

DEFINITIONS

SEC. 7. (a) Section 2(e) of the Animal Welfare Act (7 U.S.C. 2132(e)) is amended by adding after "The term 'research facility' means" the following: "each department, agency, or instrumentality of the United States which uses live animals for research or experimentation,".

(b) Section 2 of such Act is further amended by redesignating subsections (f) through (j) as subsections (j) through (n), respectively and by inserting after subsection (e) the following new subsections.

"(f) The term 'Federal agency' means an Executive agency as such term is defined in section 105 of title 5, United States Code, and with respect to any research facility means the agency from which the research facility receives a Federal award for the conduct of research, experimentation, or testing, involving the use of animals;

"(g) The term 'Federal award for the conduct of research, experimentation, or testing, involving the use of animals' means any mechanism (grant, award, loan, contract, or cooperative agreement) under which Federal funds are provided to support the conduct of such research;

"(h) The term 'quorum' means a majority of the Committee members;

"(i) The term 'Committee' means the Institutional Animal Committee established under section 13(c);".

EFFECTIVE DATE

SEC. 8. This Act shall take effect one year after the date of the enactment of this Act.

SUMMARY OF ANIMAL WELFARE ACT [AWA] AMENDMENT

RESEARCH STANDARDS

The Secretary of Agriculture shall promulgate standards for animal care; treatment and practices; standards to minimize pain; and for exercise of dogs.

CERTIFICATION PROCESS

Facilities will report annually that they are in compliance with the AWA and provide in its' justification of the research: a description of painful procedures and indicate that alternatives have been considered, assurance that standards to minimize pain are being adhered to; an explanation of any deviations from the standards.

RESEARCH REVIEW

Establishes an Institutional Animal Committee appointed by the research facility which will include one member who represents society's concerns for the welfare of animal subjects and a veterinarian. Includes trade secret protection.

COMMITTEE ACTIVITIES/INCREASED ENFORCEMENT

The committee will conduct semi-annual inspections; file reports with the research facility; and notify the institutions and appropriate federal authorities of violations. If a facility, given the opportunity to correct violations, does not adhere to the AWA, federal agencies are directed to suspend or revoke funding. The USDA Animal and Plant Health Inspection Service (APHIS) would be required to inspect facilities at least once a year, with follow-up visits until violations are corrected. APHIS would be required to inspect federal facilities.

INFORMATION SERVICE

Establishes an information service at the National Agricultural Library to work in conjunction with the National Library of Medicine to provide information on improved methods of experimentation. The data base will be made available on a voluntary basis to researchers and will focus on reducing or replacing animal use, minimizing pain and distress and preventing unintentional duplication of animal experimentation. Requires facilities to provide for instruction of personnel involved in animal care and treatment.

PENALTIES

Awarding agencies may suspend or revoke grants when facilities have been negligent of humane treatment despite notification. Fines for violators of the AWA will be increased.

By Mr. SIMPSON (for himself and Mr. SPECTER):

S. 1235. A bill to reorganize the functions of the Nuclear Regulatory Commission by abolishing the Commission and, in its place, establishing the Nuclear Regulatory Agency, in order to promote more effective and efficient nuclear licensing and regulation; to the Committee on Environment and Public Works.

NUCLEAR REGULATION REORGANIZATION ACT

Mr. SIMPSON. Mr. President, today I am introducing the "Nuclear Regulation Reorganization Act of 1985," for the purpose of abolishing the Nuclear Regulatory Commission, and in its place, establishing an independent regulatory entity, the Nuclear Regulation Agency. This new agency would be headed by a single administrator and would be responsible for carrying out those licensing and regulatory functions now exercised by the Nuclear Regulatory Commission.

When I first arrived in the Senate in January 1979, Mr. President, I assumed the role of ranking minority member of the Subcommittee on Nuclear Regulation of the Committee on Environment and Public Works. What appeared to me at the time, was a leg-